CLAIMS

1. An automatic diagnostic apparatus comprising:

a controller for controlling operation of the apparatus and for processing data;

a sensing system operably connected to the controller for performing an assay, preferably an electrochemical assay (more preferably an electrochemical immunoassay), of a sample and communicating data from said assay to said controller;

voltage supply means for applying a potential difference to said sensing system; and

output means for communicating processed data to a user.

2. An apparatus according to Claim 1, further comprising sample holding means for holding said sample.

3. An apparatus according to Claim 2 wherein said sample holding means comprises a container having a first base and a second base, said second base being raised from said first base and having a depression provided therein, such that when material comprising a heavier component and a lighter component is placed within said container and spun, said heavier component is forced towards said first base and said lighter component is forced towards and onto said second base and subsequently retained within said depression.

4. An apparatus according to Claim 2 or Claim 3, wherein said apparatus further comprises a centrifuge for spinning said sample holding means.

5. An apparatus according to any one of Claims 2 to 4, wherein said sample holding means further comprises reagent holding means.

6. An apparatus according to Claim 5, wherein said reagent holding means is a reagent cartridge comprising a body with at least one depression therein, and a removable cover sealed over said depression, wherein at least a reagent is provided within each of said at least one depression and said removable cover is provided with a bar-code on an outer side thereof, said bar-code being usable to identify said reagent(s) and/or a diagnostic test requiring said reagent(s).

7. An apparatus according to Claim 5 or Claim 6, comprising heating means for heating said reagent holding means, said heating means being controlled by said controller.

8. An apparatus according to any one of Claims I to 7, comprising input means for inputting data into said controller.

9. An apparatus according to Claim 8 wherein said input means comprises a keypad, and a scanner for scanning bar-code data.

10. An apparatus according to any preceding claim wherein said apparatus has a lid and wherein said controller is operably connected to a lid sensor for sensing whether the apparatus's lid is open or closed.

11. An apparatus according to any preceding claim wherein said controller is operably connected to a sample sensor for sensing whether a sample is present.

12. An apparatus according to any preceding claim wherein said sensing system comprises:

a electrochemical immunoassay biosensor for performing an electrochemical immunoassay of a sample; and

means for generating flow of said sample through said biosensor.

13. An apparatus according to Claim 12 wherein said biosensor comprises:

a sensor body having a sensor outlet in a part thereof;

a counter electrode having a first aperture operably connected to said sensor outlet;

a working electrode having a second aperture operably connected to said sensor outlet;

a solid phase system operably located within said working electrode; and

an inlet means to provide a sample onto said solid phase system.

14. An apparatus according to Claim 13, wherein said sensor body is manufactured from a plastics material and said working and counter electrodes are manufactured from an electrically conductive plastics material.

15. An apparatus according to Claim 12 or Claim 13, wherein said biosensor is that of GB-A-2289339.

16. An apparatus according to any one of Claims 12 to 15 wherein said means for generating said flow is a syringe.

17. An apparatus substantially as hereinbefore described and as shown in the accompanying drawings.

18. Use of an apparatus according to any one of claims 1 to 17 to diagnose and monitor a clinical condition, in particular acute myocardial infarction.

19. A method of automatic diagnosis, the method comprising the steps of:

(a) placing a sample within an automatic diagnostic apparatus;

(b) generating instructions with a controller for instructing a voltage supply means to apply a voltage to a sensing system;

(c) controlling said sensing system with said controller to perform an assay, preferably an electrochemical assay (more preferably an electrochemical immunoassay), of said sample and to generate data for output to said controller;

(d) processing said data In said controller to generate processed data; and

(e) controlling with said controller an output means to output said processed data to a user.

20. A method of automatic diagnosis according to Claim 19, conducted with an automatic diagnostic apparatus according to any one of Claims 1 to 17.

21. A disposable electrochemical immunoassay biosensor comprising:

a sensor body with a depression therein and a sensor outlet in said depression;

an apertured counter electrode provided in abutment with one side of said depression such that said counter electrode aperture communicates with said outlet;

an apertured working electrode provided in abutment with another side of said depression such that said working electrode aperture communicates with said sensor outlet;

an immunoassay system provided in close proximity to said working electrode, and

an apertured sensor inlet means also provided within said working electrode and in communication with said immunoassay system;

wherein said sensor body is manufactured from a plastics material and said working and counter electrodes are manufactured from an electrically conductive plastics material.

22. A disposable electrochemical immunoassay biosensor according to Claim 21 wherein said immunoassay system is within said working electrode.

23. A prepacked disposable diagnostic testing kit sealed with a removable cover, the kit comprising at least one disposable sample holding means, at least one disposable electrochemical biosensor, at least one disposable through-flow producing means and at least one disposable reagent cartridge, wherein said each of said at least one disposable reagent cartridge is prepacked with at least one reagent for the performance of at least one diagnostic test and then sealed with a removable seal.

24. A kit according to Claim 23, wherein said sample holding means comprises a container as defined in Claim 3.

25. A kit according to Claim 23 or Claim 24, wherein said electrochemical biosensor comprises a biosensor according to Claim 21 or Claim 22.

26. A kit according to any one of Claims 23 to 25, wherein said through flow producing means is a syringe.

27. A kit according to any one of Claims 23 to 26, wherein said at least one reagent cartridge is a cartridge as defined in Claim 6.

28. A container having a first base and a second base, said second base being raised from said first base and having a depression provided therein, such that when material comprising a heavier component and a lighter component is placed within said container and spun, said heavier component is forced towards said first base and said lighter component is forced towards and onto said second base and subsequently retained within said depression.

29. A disposable reagent cartridge comprising a body with at least one depression therein; and a removable cover sealed over said depression; wherein at least one reagent is provided within said depression and said removable cover is printed with a bar-code on an outer side thereof, said bar-code being usable to identify said reagent and/or a diagnostic test requiring that reagent.

30. A reagent cartridge according to Claim 29 comprising at least one depression filled with buffer solution.

31. A reagent cartridge according to Claim 30 comprising at least one depression filled with a dried substrate that is dissolvable by mixing with said buffer solution.

32. A reagent cartridge according to Claim 31 wherein said substrate is naphthyl phosphate.

33. A reagent cartridge according to any of Claims 29 to 32 comprising at least one depression filled with a wash solution.

34. A reagent cartridge according to any of Claims 29 to 33 comprising at least one depression filled with a conjugate solution.

35. A reagent cartridge according to Claim 34 wherein said conjugate is alkaline phosphatase, preferably having associated therewith an antibody.

36. A disposable reagent cartridge for diagnostic testing of myocardial infarction, the cartridge comprising a plastic body with four depressions therein and a removable cover sealed over said depressions; wherein a first depression is filled with a buffer solution, a second depression is filled with a wash solution, a third depression is filled with dried naphthyl phosphate, a fourth depression is filled with alkaline phosphatase, preferably associated with an antibody, and said removable cover is printed with a bar-code on an outer side thereof, said bar-code being usable to identify said contents within one or more of the depression and/or the diagnostic test.

37. A method of automatically diagnosing myocardial infarction, the method comprising monitoring ex vivo levels of one or more detectable cardiac marker proteins, such as any one or more

of CK, CK-MM, CK-MB, myoglobin, cardiac myosin light chain(s), Troponin T or Troponin I or a cardiac marker suitable for the diagnosis of acute myocardial infarction.

38. A method according to Claim 36 accomplished with the apparatus according to any one of Claims 1 to 17.

39. A conducting plastic electrode suitable for use in a diagnostic apparatus.

40. Use of a conducting plastic electrode for an electrochemical immunoassay.

41. An automatic diagnostic apparatus comprising:

a controller for controlling operation of the apparatus and for processing data;

a sensing system for performing an assay of a sample, and for communicating sensed information to the controller; and

output means for communicating processed data to the user.

42. Apparatus according to claim 42, further comprising means for supplying a power or voltage signal to the sensing system.

43. Apparatus according to claim 41 or 42, wherein the controller is operable to control at least partly the operation of the sensing system.

44. A self contained diagnostic apparatus comprising:

a centrifuge;

a system for collecting and temporarily storing material from the centrifuge after spinning;

means for transferring the collected material to or through a sensor for performing an assay on the collected material;

means for transferring one or more other materials to or through the sensor;

an electronic controller for controlling operation of the apparatus and for processing output information from the sensor.

45. Apparatus according to claim 44, further comprising means for receiving a cartridge containing said one or more other materials for the sensor, and wherein said means for transferring said one or more other materials, compress means for obtaining said materials from the cartridge and, preferably, for temporarily storing said material.

46. Apparatus according to claim 44 or 45, comprising multi-channel collecting means for handling and/or creating a plurality of samples.

47. Apparatus according to claim 44, 45 or 46 wherein the sensor interchangeable.

48. A method of automatic diagnosis, the method comprising the steps of:

operating a sensing system under the control of a controller to perform an assay of a sample and to generate output information to the controller;

processing said information in said controller; and

outputting information from the controller to the user.

49. A method according to claim 48, comprising the steps of applying a power or voltage signal to the sensing system under the control of the controller.

50. A carrier for carrying material in a centrifuge and having first and second regions such that, in use, during spinning in a centrifuge a heavier component of the material collects in one of the regions, and a lighter component of the material collects in the other regions, the carrier being configured to obstruct re-mixing of the component after spinning.

51. A carrier according to claim 50, wherein the carrier has a barrier wall between the first and second regions for obstructing mixing of the components.

52. A carrier according to claim 51, wherein the first region comprises a depression, a wall thereof forming the barrier wall.

53. A disposable reagent cartridge substantially as hereinbefore described with reference to Figures 6 and 7 of the accompanying drawings.

54. A container substantially as here before described with reference to Figure 5 of the accompanying drawings.

55. A biosensor substantially as hereinbefore described with reference to Figure 8 of the accompanying drawings.

56. A kit substantially as here before described with reference to Figure 9 of the accompanying drawings.

57. A method of automatic diagnosis substantially as hereinbefore described.

58. A method of automatically diagnosing myocardial infarction substantially as hereinbefore described.